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Supreme Court, U.S.
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No. 98-1768

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

OPPOSITION TO MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

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OPPOSITION TO MOTION OF DANEK MEDICAL, INC. FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

Respondent, Plaintiffs' Legal Committee, hereby opposes the motion of Danek Medical, Inc. for leave to file a brief as *amicus curiae* in support of Buckman Company's petition for certiorari.

First, the Rules of this Court disfavor motions of this type. *Sup. Ct. R.* 37.2(b). The purpose of an *amicus curiae* brief is to "bring[ ] to the attention of the Court relevant matter not already brought to its attention by the parties." *Sup. Ct. R.* 37.1. "An *amicus curiae* brief that does not serve this purpose burdens the Court, and its filing is not favored." *Id.* A review of Danek's summary of argument reveals that the proposed *amicus* brief presents nothing new that is relevant to Buckman's petition. In fact, the legal preemption arguments contained in the two briefs are identical. Danek's motion, therefore, is an impermissible attempt by the parties to exceed the 30-page limitation imposed on Petitioner by *Sup. Ct. R.* 33.1(g)(i) for a petition for a writ of certiorari.[1]

Second, Danek's purported reason for filing an *amicus* brief is to "assist the Court in understanding the profound impact [on Danek] of allowing" plaintiffs' fraud-on-the-FDA claims to go forward. Danek Motion at 2. Danek has argued below, however, that the Third Circuit's decision does not impact on Danek in any way whatsoever because Danek was not a party in the *Buckman* appeal and because the *Buckman* appeal involved a different manufacturer. *See, e.g.*, Excerpts from briefs filed by Danek in the remand courts opposing Plaintiffs' motions to reinstate fraud-on-the-FDA claims in light of the Third Circuit's decision (appended hereto at 3a, 5a, 11a, 13a, 17a, 19a, 22a, 26a, 28a, 32a and 34a). In either event, Buckman already has argued in its petition that the Third Circuit's decision, as part of multidistrict proceedings, has "far-reaching legal and practical effects." Pet. at 16. The *amicus* brief adds no new relevant matter.

Third, in its attempt to have the Court grant certiorari, Danek presents collateral issues which pertain only to Danek and are not germane to Buckman. In doing so, Danek misstates the facts to which the Plaintiffs' Legal Committee has not had an opportunity to respond.

For these reasons, Danek's motion for leave to file a brief as *amicus curiae* should be denied.

Respectfully submitted,

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[1] Buckman's petition already consists of 30 full pages of argument.

APPENDIX

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Barbara Bruzer and Dale Eugene Bruzer,

Plaintiffs,

v.

Danek Medical, Inc., et al.

Defendants.

Civil Action No. 3-95-971 RHK/JMM

SOFAMOR DANEK DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO REINSTATE A FRAUD-ON-THE-FDA CLAIM

INTRODUCTION

Plaintiffs' motion to reinstate the fraud-on-the-FDA claim dismissed by Judge Bechtle while this case was in MDL-1014 should be denied. Their analysis of In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereafter "Buckman" decision), is flawed.[1] Ms. Bruzer's argument regarding Buckman as "law of the case" is simply wrong, and the Third Circuit decision is therefore not controlling here. Moreover, Buckman's holding that federal law does not preempt claims of misrepresentation directed to federal agencies is contrary to federal law on preemption as it has evolved in other courts both before and after Medtronic v. Lohr, 518 U.S. 470 (1996). Most importantly, plaintiffs cite neither the law nor the evidence that they would

[1] The Third Circuit recently denied Buckman's petition for rehearing. The defendants in Buckman have filed a stay motion which indicates that a petition for *certiorari* to the United States Supreme Court will be filed.

need, under Buckman[2], to pursue a fraud-on-the-FDA claim, and completely ignore this Court's prior observations on the absence of causation and reliance in connection with this claim.

1. Neither Minnesota Law Nor The Facts Of This Case Allow Plaintiffs To Reinstate the Fraud-On-The-FDA Claim.

Plaintiffs' fraud-on-the-FDA claim is premised on the notion that defendants allegedly defrauded the FDA by requesting a clearance from the FDA to market a medical device for a specific use while intending to unlawfully promote it for another use, thereby gaining access to the market. In her effort to sidestep Minnesota law and focus on activities which have never been the subject of enforcement action by the FDA, Ms. Bruzer suggests that she has a viable claim for fraud on a federal agency involving a medical device which was used here in both an on-label and off-label way by her surgeon, Dr. Garvey, even though Dr. Garvey's medical judgment was not influenced either by the FDA or the manufacturers.

The Buckman decision does not allow these plaintiffs to reinstate a fraud-on-the-FDA claim against different defendants under Minnesota law. Buckman expressly stated:

> Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.

159 F.3d at 829. Buckman, unlike other courts, held only that the FDCA did not preempt states from allowing fraud-on-the-FDA claims. Id. at 823-26. Even if Buckman's holding on preemption applies here (which it should not), plaintiffs must still establish that Minnesota would recognize such a claim, which they do not attempt to do.

To reinstate plaintiffs' fraud-on-the-FDA claim would require an Erie prediction of Minnesota law. Buckman provides no basis for such a prediction. Rather, "[a] federal court in di-

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[2] Plaintiffs also address, in their Notice of Supplemental Authority, the impact of Buckman and the FDA's Final Rule on their negligence per se claim. These arguments are wrong for the reasons set forth in section 4 of this memorandum.

versity is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." Day & Zimmerman, Inc v. Challoner, 423 U.S. 3, 4 (1975). See also, Karas v. American Family Insurance Co., 33 F.3d 995, 1000 (8th Cir. 1994) ("[a]s a federal court, our role is to interpret state law in diversity cases and not to fashion it"). There is no more basis after Buckman than before for predicting that Minnesota would allow a private plaintiff to pursue a claim for fraud supposedly committed against a federal agency where the device is used in both an on-label and off-label way by a surgeon whose judgment was unaffected by either the FDA's position on pedicle screw use or any activities of the defendants.

The facts in Bruzer are markedly different from the factual background considered in the Buckman decision. Buckman involved a different manufacturer that obtained a §510(k) clearance from the FDA for screws to be used in the long bones of the arms and legs and purportedly intended "at the time of the application to market that device solely for another, more hazardous use." Buckman, 159 F.3d at 828. The Third Circuit expressly recognized that such facts "bear[] no resemblance" to a dual-use situation where a manufacturer "disseminat[ed] . . . information relevant to off-label use" while doctors also employed the device "for the use intended." 159 F.3d at 828 and n.7.

Here, as is so with nine of the other cases before this Court, a "dual use" unquestionably existed. The FDA clearance here provided that the screws could be labeled and marketed for use in the sacrum[3]. Sacral use of screws is undeniably a common medical procedure[4]. Here, two screws

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[3] See FDA Clearance Letter (attached as Exhibits 1-3 to the Affidavit of Richard Treharne filed herein).

[4] See Recher Affidavit, Exhibit A (Surgeon Testimony Regarding Sacral Use).

were implanted in Ms. Bruzer's sacrum, the intended use for which clearance was granted, i.e., an on-label use. Dr. Garvey also implanted screws in the pedicles at L4 and L5, using the screws in a permissible off-label manner. Because the present facts do not resemble Buckman, the Third Circuit's decision does not entitle these plaintiffs to reinstate a fraud-on-the-FDA claim.

For a number of reasons, Minnesota law would not allow a fraud claim to proceed in these circumstances. Minnesota has consistently followed a course which does not allow private enforcement of statutes which do not provide for a private cause of action. The FDCA is such a law. See 21 U.S.C. §337(a). In reality, plaintiffs' fraud-on-the-FDA claim is a disguised "unlawful promotion" claim, which is premised upon the regulations of the FDA, the FDCA and the Medical Device Amendments (MDA's). As Danek has already pointed out, plaintiffs' attempt to pursue such claims under the FDCA under the guise of negligence per se is barred under Minnesota law. See Defendant's Summary Judgment Memorandum in Bruzer, pp. 22-23; see also Jeffers v. Convoy Co., 650 F.Supp. 315 (D.Minn. 1986); Valtakis v. Putnam, 504 N.W.2d 264, 266 (Minn. App. 1993). These cases lead to the conclusion that plaintiffs' unlawful promotion claim cannot be asserted under the guise of negligence per se when the statute sought to be used to establish a breach of duty does not provide for a private right of action. As plaintiffs' fraud-on-the-FDA claim is inextricably intertwined with the federal law regulating the medical device industry, it logically follows that Minnesota courts would not allow a claim for fraud on a federal agency when the claim is based upon a federal law which precludes private enforcement. Buckman expressly leaves to the transferor courts the issue of whether such a claim can be asserted under state law, and Minnesota would not recognize a claim of this sort.

Moreover, the statement of intended use made by Danek in its application for a marketing clearance was not untrue, and cannot be the basis for a fraud claim. Off-label use of medical devices

As Buckman does not apply to this case, and as Minnesota law would not recognize a fraud claim of this sort under the circumstances, plaintiffs' motion to reinstate this claim should be denied.

2. Plaintiffs Wrongly Assert that Buckman is the Law of the Case.

Because neither the facts nor the law allow plaintiffs to reinstate their fraud-on-the-FDA claim, they contend that "law of the case" prohibits this Court from making an independent ruling under Minnesota law. Pl. Br. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases on page 4 of plaintiffs' brief involve a decision made, as here, after remand. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F.Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) §31.133, at 255 (1995) (after remand, the transferor court has "exclusive jurisdiction and further proceedings in the [MDL] court with respect to a remanded case are not authorized").

Second, and more fundamentally, Danek was not a party in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure §4478, at 832 (Supp. 1998); see In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("[w]here there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to appeal, and prevents the challenged decision from becoming the law of the case").[7] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing of an amicus brief has never been enough to bind a non-party to the result

[7] Accord, e.g., Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990); Gage v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982).[8]

Third, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And **we would invite the transferor court to revisit that issue**. If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or Fifth [Circuits] can say, thank you very mueh, Judge Bechtle. We feel differently in this circuit.

Recher Affidavit, Exhibit B; In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added). For each of these reasons, law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

3. **Claims of Fraud on a Federal Agency are Preempted under Federal Law.**

Several courts have already held, contrary to Buckman, that allegations attacking federal administrative decisions as "fraudulent" are preempted -- because such claims inherently conflict with whatever agency action they seek to invalidate. This conflict is particularly glaring since, as already discussed, the FDA's 1998 Final Rule (which was not before the Buckman court) rejected the same allegations made here.

Plaintiffs challenge the FDA's clearance allowing TSRH screws to be labeled and marketed for use in the sacrum. This administrative decision was not made in a vacuum, but was made in a

[8] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F.2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); TRW, Inc. v. Ellipse Corp., 495 F.2d 314, 318 (7th Cir. 1974); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra §4451, at 377-78 n. 15 (Supp. 1998); 4 Am. Jur. 2d, Amicus Curiae §6, at 327-28 & n. 43 (1995).

law. Under Minnesota law, there can be no negligence per se claim for promotional activities which allegedly violate federal law. Nothing in Buckman or the concept of federal preemption overrides Minnesota's policy of judicial restraint in such an instance.

CONCLUSION

For all of the above reasons, plaintiffs' motion to reinstate a claim of fraud-on-the-FDA is unsupported by any facts, contrary to law, and should therefore be denied.

Dated: February 22, 1999.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

DENISE ALMOND and JOHN ALMOND, Husband	:	
Plaintiffs,	:	C.A. No. C-1-94-755
v.	:	(Judge Herman J. Weber)
DANEK MEDICAL, INC.	:	
Defendant	:	

DEFENDANT DANEK MEDICAL, INC.'S BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR RELIEF FROM JUDGMENT DISMISSING FRAUD-ON-THE-FDA AND NEGLIGENCE PER SE CLAIMS

I. INTRODUCTION

Defendant Danek Medical Inc. opposes Plaintiffs' Motion for Relief From Judgment on the ground that the decision of the Court of Appeals for the Third Circuit on which it relies has no force or effect because the mandate is stayed pending a ruling on a petition for panel rehearing. In addition, even if the decision were to become the law of the Third Circuit, it would not be the law of this case and therefore would not be controlling, but at most persuasive authority. Finally, for a host of reasons, Danek is entitled to summary judgment on all claims irrespective of the reach of statutory preemption under the Medical Device Amendments. In particular, nothing in Buckman disturbs this Court's decision that Ohio would not allow recovery for negligence per se based upon alleged violations of the federal Food, Drug and Cosmetic Act ("FDCA").

This case was transferred to MDL-1014 on March 1, 1995. On March 28, 1997, Judge Bechtle dismissed all claims by MDL bone screw plaintiffs alleging fraud-on-the-FDA (PTO 845). Buckman Company, sued as a regulatory consultant to another manufacturer of medical

devices, Acro Med Corporation, had only fraud-on-the-FDA claims pending against it. PTO No. 900, entered by Judge Bechtle on May 12, 1997, dismissed such claims against Buckman. On September 12, 1997, Judge Bechtle certified the Buckman dismissal as a final order under Fed. R. Civ. P. 54(b) (PTO 1067). The MDL plaintiffs appealed dismissal of the fraud-on-the-FDA claim as to Buckman.

On November 17, 1998, a dividend panel of the Court of Appeals for the Third Circuit issued an opinion holding that Judge Bechtle had erred in ruling that the claim against Buckman was preempted by the FDCA. In re Orthopedic Bone Screw Products Liab. Litig., 159 F.3d 817 (3d Cir. 1998) ("Buckman"). On December 1, 1998, Buckman Company filed a timely petition for panel rehearing and suggestion of rehearing en banc. As of December 28, 1998, that petition remains pending. On December 2, 1998, Ms. Almond filed a Motion for Relief from Judgment explicitly based on the Third Circuit's Buckman decision.

In the meantime, this case was remanded from MDL-1014 to this Court on August 22, 1997, or well prior to the Buckman decision. On March 2, 1998, this Court entered its Amended Order granting partial summary judgment in favor of Danek. Among the claims dismissed were fraud-on-the-FDA and negligence per se. Design defect, inadequate warnings, and misrepresentation claims survived summary judgment.

II. ARGUMENT

A. PLAINTIFFS' MOTION FOR RELIEF FROM JUDGMENT IS PREMATURE

Plaintiffs' Rule 60(b) is based entirely on the Buckman opinion, but the Third Circuit's mandate has not yet issued in that case. Buckman's timely petition for panel rehearing

automatically stays the Third Circuit's mandate. A timely petition for rehearing pursuant to Fed. R. App. P. 40(a) automatically stays issuance of the mandate until issues raised by the petition are resolved. Fed. R. App. P. 41(a); Fine v. Bellefonte Underwriters Ins. Co., 758 F.2d 50, 53 (2d Cir. 1985). Until the Third Circuit's mandate issues, jurisdiction over the matter resides exclusively with the court of appeals. If the petition for rehearing is denied, the mandate will issue within seven days of the date of the order. Fed. R. App. P. 41. When the mandate issues, jurisdiction over the matter will be restored to the district court. Ostrer v. United States, 584 F.2d 594, 598 (2d Cir. 1978). See also 20 Moore's Federal Practice §341.12[2] at 341-7 (3d ed. 1998).

Plainly enough, Buckman has not changed Buckman's legal status vis-a-vis the plaintiffs who have sued it; until the mandate issues, if ever, those claims are dismissed. If Buckman is ineffective to change the rights of the litigants to the appeal in which the decision was rendered, and will remain so until the mandate issues, it can hardly have more effect on persons who were not parties to the appeal. In short, Buckman is of considerable interest for what it may portend, but at the moment it is not authority for doing anything, including reinstating claims that Judge Bechtle dismissed. Plaintiffs' motion for reinstatement is premature.

B. THE BUCKMAN DECISION IS NOT THE LAW OF THIS CASE

Plaintiffs argue Buckman as "law of this case." Br. at 3. Plaintiffs are wrong. First, this case was remanded before the Buckman appeal was even taken, let alone decided. "After remand, the transferor court has exclusive jurisdiction and further proceedings in the [MDL] court with respect to a remanded case are not authorized." Manual for Complex Litigation (3d) §31.133, at 255 (1995). Accordingly, the Third Circuit's post-remand decision thus "has no effect" here

except what this Court chooses to give it. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981).

More fundamentally, Buckman cannot be law of the case because Danek was not a party to the Buckman appeal.[4] Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure §4478, at 832 (Supp. 1998). "A review of the case law reveals that courts will refuse to apply virtual representation simply to preclude a nonparty from relitigating issues that have been lost after vigorous advocacy by a party who seems to hold an interest identical to the interests of the nonparty." Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995).[5] The Buckman/AcroMed regulatory history is not the regulatory history of Danek's TSRH sacral screws, either as pleaded by plaintiffs or as the evidence will show. Hence the court of appeals' ruling as to Buckman did not decide the legal sufficiency of the complaint in this case, let alone whether plaintiffs' claims can withstand summary judgment scrutiny. Law of the case cannot apply, and Buckman is not controlling in this case.

C. THE BUCKMAN DECISION DOES NOT AFFECT PLAINTIFFS' NEGLIGENCE PER SE CLAIM

Plaintiffs erroneously argue that Buckman resuscitates their negligence per se claim. Negligence per se was not before the Third Circuit, and plaintiffs' negligence per se claims remain

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[4] Indeed, Danek attempted to participate as a party in the Buckman appeal, but was relegated to *amicus curiae* status upon plaintiffs' motion. 159 F.3d at 821, n.3.

[5] Accord, e.g., In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990).

barred under Ohio law for all the reasons stated in Danek's summary judgment briefing.[1] The Third Circuit did not decide any state-law issues. 159 F.3d at 829 ("We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted."). It held only that the absence of a private right of action for violations of the FDCA or MDA and a provision conferring FDCA enforcement powers solely upon "the United States," were insufficient indicia of Congressional intent to preempt claims of fraud-on-the-FDA. Id. at 824-825. Buckman provides no grounds for relief from judgment here because Danek never asserted statutory preemption as a defense to negligence per se.

Buckman did not affect Ohio negligence per se law. Ohio does not treat statutory violations as negligence per se unless the statute contemplates private litigation of such violations. In Renfro v. Black, 52 Ohio St. 3d 27, 32, 556 N.E.2d 150, 155 (1990), the Ohio Supreme Court affirmed the trial court's refusal even to admit evidence of alleged FDCA violations because "there is no private civil cause of action for monetary recovery based upon alleged violations of the Federal Food, Drug and Cosmetic Act." The Supreme Court and the Sixth Circuit concur.[2]

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[1] See Defendant Danek Medical, Inc.'s Motion for Summary Judgment and Memorandum of Law in Support filed on January 2, 1998 and Danek Medical, Inc.'s Reply to Plaintiffs' Opposition to Summary Judgment filed on February 13, 1998.

[2] Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2251 (1996) ("there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action"); Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804, 812 n.10 (1986) ("where Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless'") (citation omitted).

The Sixth Circuit stated, with respect to the FDCA, that a "state's ability to use a federal statute violation as a basis for state tort liability and negligence *per se* depends on the intent of Congress, and not merely on the intent of the state. . . . [T]he congressional decision not to provide a private cause of action under the FDCA becomes quite important in considering the propriety of a state negligence per se action for violation of the FDCA." In re Bendectin Litigation, 857 F.2d 290, 313-14 (6th Cir. 1988) (citation omitted), (continued...)

Spinal Systems 63 Fed. Reg. 40025 (FDA July 27, 1998).[1] The Final Rule demonstrates that the FDA investigated plaintiffs' fraud charges,[2] determined that prior screw clearances should be retained, and concluded that it was not defrauded.[3] The FDA's Final Rule defeats causation as a matter of law because it precludes any contention that, but for the alleged "fraud," the FDA might have done something materially different."The discussion in the Federal Register shows that the FDA concluded that it was never defrauded by the manufacturers of orthopedic bone screws. These claims have no merit." Estep v. Danek Medical, Inc., No. 1:96CV2580, slip op. at 12 (N.D. Ohio Oct. 5, 1998) (Exhibit A attached), reconsideration granted on other grounds (Dec. 8, 1998) (summary judgment entered against negligence per se) (Exhibit B attached). Cf. Stanton v. Astra Pharmaceutical Products, Inc., 718 F.2d 553 (F.2d 1983)(evidence of causation legally sufficient, if barely so, where four expert witnesses gave testimony from which the jury could have inferred that the FDA would have required notice to the medical community of adverse effects associated with defendant's drug if defendant had complied with requirement to report adverse reactions to drug).

Third, the Third Circuit specifically limited itself to fraud allegations against another manufacturer and did not consider Danek or its devices. Those allegations were that AcroMed

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[1] The FDA's Final Rule reclassified "pedicle screw spinal systems" from Class III to Class II devices for several indications, including one of Ms. Almond's specific problems – scoliosis. 63 Fed. Reg. at 40035.

[2] In December, 1995, Judge Bechtle permitted plaintiffs to submit their allegations to the FDA as public comments to the FDA's proposed reclassification of spinal implants. In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, 1995 WL 764580 (E.D. Pa. Dec. 14, 1995) (PTO 179).

[3] 63 Fed. Reg. at 40031, 40039 (pre-1995 clearances not misleading; continuing to use stated intended uses); id. at 40028-30 (cohort study and other data not falsified); at 40030 (rejecting allegations of undisclosed financial relationships); at 40032-33 (Danek 1/20/95 clearance not fraudulent).

intended "at the time of the application to market that device solely for another, more hazardous use." 159 F.3d at 828. That claim "bears no resemblance" to a dual-use situation where a manufacturer "disseminat[ed]. . .information relevant to off-label use" while doctors also employed the device "for the use intended." Id. at 828n.7 (emphasis added).

In this case it is undisputed that the broken screw allegations relate to bone screws implanted in Ms. Almond's sacrum. [9] It is also undisputed that TSRH screws had been cleared for use in the sacrum. [10] The undisputed facts here thus "bear[] no resemblance," id., to the fraud allegations in Buckman. Rather they demonstrate that the Danek's application for clearance to market the TSRH screws for sacral fixation was not "simply. . . a pretext." Id. at 820. Summary judgment against plaintiffs' fraud-on-the-FDA claim would thus be appropriate, even under Buckman. Ms. Almond's own surgery establishes that sacral fixation was a bona fide "intended use." There was no fraudulent misrepresentation to the FDA.

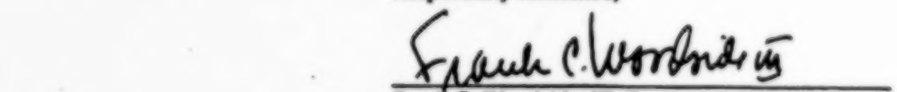
[9] See Defendant Danek Medical, Inc.'s Motion for Summary Judgment and Memorandum of Law (filed on January 2, 1998) at pp. 7 and 21 and Danek Medical, Inc.'s Reply to Plaintiffs' Opposition to Summary Judgment (filed on February 13, 1998) at pp. 2 and 11.

[10] TSRH screws were cleared for the "intended use" of sacral fixation beginning in 1989. FDA (4/6/89), (11/6/90), (12/10/90), (9/6/91), (12/2/91), (1/10/92), (1/22/92) clearance letters (Exhibits C - I attached).

III. CONCLUSION

For all of the reasons stated above, this Court should deny Plaintiffs' Motion for Relief from Judgment and sustain summary judgment in favor of Danek Medical, Inc. on the claims of fraud-on-the-FDA and negligence per se.

Respectfully submitted,



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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

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SCOTT McCOLLIN and KAREN McCOLLIN, Plaintiffs, v. DANEK MEDICAL, INC., et al., Defendants.	DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO REINSTATE A FRAUD-ON-THE-FDA CLAIM Case No. 2:95CV1097C

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Defendants Danek Medical, Inc., Sofamor Danek Group, Inc., Sofamor, S.N.C., Sofamor, Inc. and Warsaw Orthopedic, Inc. (collectively, "Sofamor Danek"), submit this Memorandum in opposition to plaintiffs' Motion to Reinstate Plaintiff's Fraud-on-the-FDA claim.

I. Introduction

Plaintiffs' motion to reinstate the fraud-on-the-FDA claim dismissed by Judge Bechtle while this case was in MDL-1014 should be denied. Their analysis of In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereafter "Buckman" decision), is flawed. Their argument regarding Buckman as "law of the case" is simply wrong.

Most importantly, plaintiffs cite neither the law nor the evidence they would need, under Buckman, to pursue a fraud-on-the-FDA claim.

II. Neither Utah Law Nor The Facts Of This Case Allow Plaintiffs To Reinstate Fraud On The FDA.

The Buckman decision does not allow these plaintiffs to reinstate a fraud-on-the-FDA claim against different defendants under the law of this jurisdiction. Buckman expressly stated:

> Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.

159 F.2d at 829. Buckman held only that the FDCA did not preempt states from allowing fraud-on-the-FDA claims. Id. at 823-26. But plaintiffs must still establish that Utah would recognize such a claim. Plaintiffs offer no such argument. Indeed, they ignore Utah law completely.[1]

To reinstate plaintiffs' fraud-on-the-FDA claim would require an Erie prediction of Utah law. Buckman provides no basis for such a prediction. Rather, "[a] federal court in diversity is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975). "As a federal court, we are generally reticent to expand state law without clear guidance from its highest court."" Taylor v. Phelan, 9 F.3d 882, 887 (10th Cir. 1993).

There is no more basis after Buckman than before for predicting that Utah would allow plaintiffs to pursue fraud supposedly committed against the FDA.

The facts of this case also bar plaintiffs from reinstating fraud on the FDA at this late juncture. Buckman involved a different manufacturer that purportedly intended "at the time of

[1] The linchpin of the Third Circuit's generic state-law analysis, § 310 of the Restatement (Second) of Torts (see 159 F.3d at 826-27), has not been adopted in this state, and there is no precedent allowing fraud claims based upon statements allegedly made to a government agency.

the application to market that device solely for another, more hazardous use." Buckman, 159 F.3d at 828. The Third Circuit itself realized that such facts "bear[] no resemblance" to a dual-use situation where a manufacturer "disseminat[ed] . . . information relevant to off-label use" while doctors also employed the device "for the use intended." 159 F.3d at 828 & n.7.

The FDA clearance in this case involved sacral use—and sacral use of screws is undeniably a common medical procedure.[2] Because the present facts do not resemble Buckman, the Third Circuit's decision does not entitle these plaintiffs to reinstate a fraud-on-the-FDA claim.

Moreover, Buckman was limited to the pleadings and did not consider FDA's Final Rule on the Classification and Reclassification of Pedicle Screw Spinal Systems. 63 Fed. Reg. 40025 (FDA July 27, 1998) (Exh. C). The Final Rule demonstrates that the FDA investigated the same fraud charges, determined that prior screw clearances should be retained, and concluded that it was not defrauded.[3] The FDA expressly determined that the products involved in this case do not "present a substantial deception." Id. at 40035-36. Plaintiffs can never prove reliance or causation because the 1998 Final Rule eliminates any claim that, but for alleged "fraud," the FDA might have done something materially different. See Buckman, 159 F.3d at 827 (evidence that different FDA action would have prevented injury is part of "minimum quantum of evidence" necessary to make fraud-on-the-FDA claim). Thus, the "discussion in the Federal Register shows that the FDA concluded that it was never defrauded by the manufacturers of

[2] See FDA Clearance Letter (Exh. A); Surgeon Testimony Regarding Sacral Use (Exh. B).

[3] 63 Fed. Reg. at 40031 (item 8), 40039 (item 44) (pre-1995 clearances not misleading; continuing to use stated intended uses); id. at 40028-30 (items 1-3) (data not falsified); at 40030 (item 3) (rejecting allegations of undisclosed financial relationships); at 40032-33 (items 13-16) (Danek 1/20/95 clearance not fraudulent).

orthopedic bone screws. These claims have no merit." Estep v. Danek Medical, Inc., No. 1:96CV2580, slip op. at 12 (N.D. Ohio Oct. 5, 1998) (Exh. D).

III. Plaintiffs Wrongly Assert Law Of The Case.

Because neither the facts nor the law allow plaintiffs to reinstate fraud on the FDA, they contend that "law of the case" prohibits this Court from making an independent ruling under Utah law. Pl. br. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases on pages four-and five of plaintiffs' brief involve a decision made, as here, after remand. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) § 31.133, at 255 (1995).

Second, and most fundamentally, Sofamor Danek was not a party in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure § 4478, at 832 (Supp. 1998); see In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("Where there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to appeal, and prevents the challenged decision from becoming the law of the case.").[4] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing of an amicus brief has never been

[4] Accord, e.g., Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990); Gage v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

enough to bind a non-party to the result of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982).[5]

Finally, Judge Bechtle did not intend for preemption rulings in MDL-1014 to be law of the case. Quite the opposite, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And **we would invite the transferor court to revisit that issue.** If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or fifth [Circuits] can say, thank you very much, Judge Bechtle. We feel differently in this circuit.

In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014 (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added) (Exh. E). For each of these reasons, law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

IV. Conclusion

For all of the above reasons, plaintiffs' motion to reinstate a claim of fraud on the FDA is unsupported by any facts and is contrary to law, and should therefore be denied.

DATED this 11th day of February, 1999.

RAY, QUINNEY & NEBEKER

Paul S. Felt
Joni J. Jones
Attorneys for Defendants

[5] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F 2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); TRW, Inc. v. Ellipse Corp., 495 F.2d 314, 318 (7th Cir. 1974); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra § 4451, at 377-78 n.15 (Supp 1998); 4 Am. Jur. 2d, Amicus Curiae § 6, at 327-28 & n.43 (1995).

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
(Northern Division)

JOSEPH STRANGE,

Plaintiff,

v.

SOFAMOR DANEK GROUP, INC., et al.,

Defendants.

Civil Action No. Y 95-3193

DANEK DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO REINSTATE FRAUD-ON-THE-FDA CLAIM

Defendants, Sofamor Danek Group, Inc. Danek Medical Inc., Warsaw Orthopedic, Inc., Sofamor Inc., and Sofamor S.N.C. (hereinafter "Danek" or "Danek Defendants"), respectfully submit this Memorandum in Opposition to Plaintiff's Motion to Reinstate Plaintiff's "Fraud-on-the-FDA" Claim.

I. INTRODUCTION

In November 1998, Plaintiff filed with this Court a "Notice of Recent Authority" purportedly affecting Danek Defendants' entitlement to summary judgment on Plaintiff's negligence per se claim and Plaintiff's then dismissed claim for "Fraud-on-the-FDA." In support of that pleading, Plaintiff relied on the then recent opinion of the Third Circuit in In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereinafter "Buckman" decision), which held, over a dissenting opinion and contrary to the decisions of several other Circuits, that the Medical Device Amendments of the Federal Food, Drug and

Circuit's decision. Pl.'s Memo. in Supp. of Mot. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases cited by Plaintiff involve a decision made, as here, after remand. See, Pl.'s Memo. In Supp. Of Mot. at 4. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) §31.133, at 255 (1995). See generally 15 C. WRIGHT, A. MILLER & E. COOPER, FEDERAL PRACTICE AND PROCEDURE, § 3862 at 508-9 and n.30 ("Of course, once a case has been remanded to the transferor district and a final judgment has been entered, any appeal may include objections to errors allegedly committed by the transferee judge.")

Second, and more fundamentally, Danek Defendants were not parties in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE §4478, at 832 (Supp. 1998); see In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("[w]here there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to appeal, and prevents the challenged decision from becoming the law of the case").[1] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing

[1] Accord, e.g., Rechsteiner v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Orr, 903 F.2d 1240, 1242 (9th Cir. 1990); Gass v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

of an amicus brief has never been enough to bind a non-party to the result of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982).[2]

Third, Judge Bechtle did not intend for preemption rulings in MDL-1014 to be law of the case. Quite the opposite, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And **we would invite the transferor court to revisit that issue.** If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or Fifth [Circuits] can say, thank you very much, Judge Bechtle. We feel differently in this circuit.

In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added)[3]. For each of these reasons, the doctrine of law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

2. ***Fraud On The FDA Is Preempted.*** Although the Fourth Circuit has not addressed this issue precisely, the other federal circuits that have considered these issues - the Fifth, Seventh, and Eleventh Circuits - have already held, contrary to Buckman, that allegations attacking federal administrative decisions as "fraudulent" are preempted because such claims inherently conflict with whatever agency action they seek to invalidate. See Reeves v.

[2] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F.2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); D.R.W., Inc. v. Fluor Corp., 495 F.2d 314, 318 (7th Cir. 1974); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra §4451, at 377-78 n. 15 (Supp. 1998); 4 Am. Jur. 2d, Amicus Curiae §4, at 327-28 & n. 43 (1995).

[3] For the Court's convenience, a copy of the applicable portion of this transcript is attached hereto and incorporated herein by reference as Exhibit A.

BEST AVAILABLE COPY

III. CONCLUSION

For the reasons stated herein, and for the reasons stated in Danek Defendants Memorandum of Law in Support of Motion for Summary Judgment, Danek's Reply to Plaintiff's Opposition to that Motion, and Danek Defendants' Memorandum in Opposition to Plaintiff's Notice of Recent Authority, Plaintiff's Motion to Reinstate his Fraud on the FDA claim should be denied.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
HAMMOND, INDIANA

EDWARD M. PARKS, Plaintiff, vs. DANEK MEDICAL, INC., Defendant.	)	Cause No. 2:95 CV 206

DEFENDANT'S MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO REINSTATE A FRAUD-ON-THE-FDA CLAIM

Plaintiff's motion to reinstate the fraud-on-the-FDA claim dismissed by Judge Bechtle while this case was in MDL-1014 should be denied. First, Plaintiff's analysis of In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) (hereafter "Buckman" decision), is flawed. Second, Plaintiff's argument regarding Buckman as "law of the case" is simply wrong, and Buckman is contrary to controlling precedent in this circuit. Most importantly, Plaintiff cites neither the law nor the evidence that he would need, under Buckman, to pursue a fraud-on-the-FDA claim.

I. Neither Indiana Law Nor The Facts Of This Case Allow Plaintiff To Reinstate Fraud On The FDA.

The Buckman decision does not allow Plaintiff in this case to reinstate a fraud-on-the-FDA claim against different defendants under the law of this jurisdiction. Buckman expressly stated:

> Our holding is a narrow one. We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.

159 F.2d at 829. Buckman held only that the FDCA did not preempt states from allowing fraud-on-the-FDA claims. Id. at 823-26. Plaintiff must still establish that Indiana would recognize such a claim. But, Plaintiff offers no such argument. Indeed, he ignores Indiana law completely.[1]

To reinstate Plaintiff's fraud-on-the-FDA claim would require an Erie prediction of Indiana law. Buckman provides no basis for such a prediction. Rather, "[a] federal court in diversity is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." Day & Zimmerman, Inc. v. Challoner, 423 U.S. 3, 4 (1975). "When we are faced with opposing plausible interpretations of state law, we generally choose the narrower interpretation which restricts liability." Birchler v. Gehl Co., 88 F.3d 518, 521 (7th Cir. 1996). "Plaintiffs seeking to bring novel state law claims should present those claims initially in state court." Shields Enterprises, Inc. v. First Chicago Corp., 975 F.2d 1290, 1298 (7th Cir. 1992) (citations and quotation marks omitted). Thus, there is no more basis after Buckman than before for predicting that Indiana would allow Plaintiff to pursue fraud supposedly committed against the FDA.

The facts of this case also bar Plaintiff from reinstating fraud on the FDA at this late juncture. Buckman involved a different manufacturer that purportedly intended "at the time of the application to market that device solely for another, more hazardous use." Buckman,

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[1]The linchpin of the Third Circuit's generic state-law analysis, §310 of the Restatement (Second) of Torts (see 159 F.3d at 826-27), has not been adopted in this state, and there is no precedent allowing fraud claims based upon statements allegedly made to a government agency.

159 F.3d at 828. The Third Circuit itself realized that such facts "bear[] no resemblance" to a dual-use situation where a manufacturer "disseminat[ed]...information relevant to off-label use" while doctors also employed the device "for the use intended." 159 F.3d at 828 & n.7.

The FDA clearance in this case involved sacral use -- and sacral use of screws is undeniably a common medical procedure.[2] Because the present facts do not resemble Buckman, the Third Circuit's decision does not entitle these plaintiffs to reinstate a fraud-on-the-FDA claim.

Moreover, Buckman was limited to the pleadings and did not consider FDA's Final Rule on the Classification and Reclassification of Pedicle Screw Spinal Systems. 63 Fed. Reg. 40025 (FDA July 27, 1998) (Exh. C). The Final Rule demonstrates that the FDA investigated the same fraud charges, determined that prior screw clearances should be retained, and concluded that it was not defrauded.[3] The FDA expressly determined that the products involved in this case do not "present a substantial deception." Id. at 40035-36. Plaintiff can never prove reliance or causation because the 1998 Final Rule eliminates any claim that, but for alleged "fraud," the FDA might have done something materially different. See Buckman, 159 F.3d at 827 (evidence that different FDA action would have prevented injury is part of "minimum quantum of evidence" necessary to make fraud-on-the-FDA

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[2]See FDA Clearance Letter (Exh. A); Surgeon Testimony Regarding Sacral Use (Exh. B).

[3]63 Fed. Reg. at 40031 (item 8), 40039 (item 44) (pre-1995 clearances not misleading; continuing to use stated intended uses); id. at 40028-30 (items 1-3) (data not falsified); at 40030 (item 3) (rejecting allegations of undisclosed financial relationships); at 40032-33 (items 13-16) (Danek 1/20/95 clearance not fraudulent). See also Defendant's Reply Brief in Support of Motion for Summary Judgment, page 20.

claim). Thus, the "discussion in the Federal Register shows that the FDA concluded that it was never defrauded by the manufacturers of orthopedic bone screws. These claims have no merit." Estep v. Danek Medical, Inc., No. 1:96CV2580, slip op. at 12 (N.D. Ohio Oct. 5, 1998) (Exh. D).

II. Plaintiff Wrongly Asserts Law Of The Case.

Because neither the facts nor the law allows Plaintiff to reinstate fraud on the FDA, he contends that "law of the case" prohibits this Court from making an independent ruling under Indiana law. Pl. br. at 3-5. This argument is meritless on several levels.

First, law of the case in multi-district litigation applies only to rulings that occur before an action is remanded. None of the cases on page four (4) of Plaintiff's brief involve a decision made, as here, after remand. Once remand has taken place, any MDL jurisdiction that might have supported law of the case no longer exists. In re Upjohn Co. Antibiotic "Cleocin" Products Liability Litigation, 508 F. Supp. 1020, 1021 (E.D. Mich. 1981); Manual for Complex Litigation (3d) §31.133, at 255 (1995).

Second, and more fundamentally, Danek was not a party in the Buckman appeal. Law of the case "does not apply to nonparties" who have not had their day in court. 4A C. Wright & A. Miller, Federal Practice & Procedure §4478, at 832 (Supp. 1998). See also In re DG Acquisition Corp., 151 F.3d 75, 86 (2d Cir. 1998) ("[w]here there has been no review even though appeal has been taken, it is equivalent to the party not having had an opportunity to

appeal, and prevents the challenged decision from becoming the law of the case").[4] Danek appeared only as *amicus curiae* in Buckman. 159 F.3d at 821 n.3. "[T]he filing of an amicus brief has never been enough to bind a non-party to the result of a proceeding." Munoz v. County of Imperial, 667 F.2d 811, 816 (9th Cir.), cert. denied, 459 U.S. 825 (1982); TRW, Inc. v. Ellipse Corp., 495 F.2d 314, 318 (7th Cir. 1974).[5]

Third, Judge Bechtle recognized that differences between the circuits on medical device preemption required each remand court to be free to apply its own circuit's law:

> If nothing else changes at this moment, if for example the Supreme Court entered an order on Lohr that remanded that case for some reason, the Court wouldn't change its ruling here. It would simply, on remand, tell the transferor court on the remand order, this Court has ruled in accordance with Third Circuit law that the following claims cannot be advanced. And we would invite the transferor court to revisit that issue. If that circuit binds that transferor court differently, that's not a difficult thing to do, that's an easy thing to do, the judge in the Eighth, First, or Fifth [Circuits] can say, thank you very much, Judge Bechtle. We feel differently in this circuit.

In re Orthopedic Bone Screw Products Liability Litigation, MDL-1014, (4/11/96) Hearing Tr. at 29-30 (E.D. Pa.) (emphasis added) (Exh. E). For each of these reasons, law of the case is entirely inapplicable, and nothing obligates this Court to follow the Buckman decision.

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[4] Accord, e.g., Becherer v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 43 F.3d 1054, 1070 (6th Cir. 1995); United States v. Guy, 903 F.2d 1240, 1242 (9th Cir. 1990); Gage v. General Motors Corp., 796 F.2d 345, 349 (10th Cir. 1986).

[5] Accord, e.g., Stryker v. Crane, 123 U.S. 527, 540 (1887); United States v. Michigan, 940 F.2d 143, 165 (6th Cir. 1991); Adams v. Bell, 711 F.2d 161, 197 n.128 (D.C. Cir. 1983), cert. denied, 465 U.S. 1021 (1984); Boeing Airplane Co. v. Aeronautical Industrial District, 91 F. Supp. 596, 602 (W.D. Wash. 1950), aff'd, 188 F.2d 359 (9th Cir. 1951); 18 Wright & Miller, supra §4451, at 377-78 n. 15 (Supp. 1998); 4 Am. Jur. 2d, Amicus Curiae §6, at 327-28 & n. 43 (1995).

v. Upjohn Co., 985 F.2d 516, 518-19 (11th Cir.) (same; fraud on the Environmental Protection Agency), cert. denied, 510 U.S. 913 (1993).

As Mitchell held, nothing in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), requires a different result. A majority of the court in Medtronic specifically recognized that preemption could occur by virtue of direct conflict. Id. at 503, 507-08. Even Buckman "d[id] not rule out the possibility that there may be some areas of preemption. . .based on clear and direct conflicts between the requirements of state law and those of the FDCA." 159 F.3d at 826.[6] Under Mitchell, preemption is another ground upon which plaintiffs' attempt to reinstate fraud on the FDA must fail.

IV. Conclusion

For all of the above reasons, Plaintiff's motion to reinstate a claim of fraud on the FDA is unsupported by any facts, contrary to law, and should therefore be denied.

Respectfully submitted,

Robert F. Wagner, #1066-49

Dina M. Cox, #18590-49

[6]The most serious flaw in the Buckman court's reasoning was its reliance upon a portion of the Medtronic decision that did not command a majority of the Supreme Court. See 159 F.3d at 825 (following Medtronic, 518 U.S. at 487 (plurality)). In "splintered" Supreme Court decisions, however, "the holding of the Court may be viewed as that position taken by those Members who concurred in the judgment on the narrowest grounds." Marks v. United States, 430 U.S. 188, 193 (1977).

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
Roanoke Division

LEILA HARTWELL WILLIAM G. HARTWELL and JENNIFER STILL ROBERT STILL	)	
Plaintiffs,	)	
v.	)	Civil Action No. 95-1134-R
DANEK MEDICAL, INC., et al.,	)	
Defendants.	)	

DEFENDANTS' SUPPLEMENTAL MEMORANDUM REGARDING PLAINTIFFS' CLAIMS OF FRAUD-ON-THE-FDA

Pursuant to the Court's instruction at the November 19, 1998 hearing, defendants Danek Medical, Inc., Sofamor Danek Group, Inc., Sofamor, Inc. and Sofamor, S.N.C. (collectively "Danek") submit this brief to address the Third Circuit's recent decision reversing the dismissal of a fraud-on-the-FDA claim against the Buckman Company in the MDL proceedings. In re: Orthopedic Bone Screw Products Liab. Litig., 1998 WL 793200 (3d Cir. Nov. 17, 1998) (attached as Exh. A). As set out below, the Third Circuit decision is not binding on this Court, is contrary to Virginia law and Fourth Circuit precedent, and is factually inapposite. Moreover, plaintiffs cannot establish that any alleged fraudulent representations by Danek caused their injuries. As a result, this Court should deny any motion by the plaintiffs to reinstate their claim of fraud-on-the-FDA or to reconsider Judge Bechtle's decision dismissing that claim and enter summary judgment in favor of Danek on all claims.

impossible to predict, from the bare pleadings, that no state in the country would allow a fraud-on-the-FDA claim under state law. Id. *11-*13.

Significantly, the Third Circuit's decision dealt only with a claim of fraud-on-the-FDA against the Buckman Company. Orthopedic Bone Screw, 1998 WL 793200 at *2 ("Buckman is a regulatory consultant. . .retained by AcroMed").[1] Thus, it does not address allegations relating to Danek or its devices. Moreover, the Court itself pointed out the limited nature of its decision:

> Our holding is a narrow one. ***We do not hold that any of the plaintiffs have stated a claim under state law upon which relief could be granted.*** Neither we nor the district court is in a position to do that before identifying, with the help of the parties, the governing law or laws. Rather, we hold that (1) the plaintiffs' "fraud on the FDA" theory of liability is not so at odds with traditional principles of tort law that Buckman is entitled to a dismissal of all claims against it at this stage; and (2) if the state law of fraudulent misrepresentation applicable in one or more of these cases would impose liability on Buckman in the circumstances alleged, that law would not be preempted by the MDA.

Orthopedic Bone Screw, 1998 WL 793200 at *14 (emphasis added). In addition, the Third Circuit's decision is not final. The Buckman Company will seek re-hearing *en banc*, and, if that is unsuccessful, a review by the Supreme Court.

While the Third Circuit's decision theoretically opens the way for this Court to consider reinstatement of plaintiffs' fraud-on-the-FDA claim, it does not prevent judgment in favor of Danek in this case. This case is no longer part of MDL-1014, thus the Third Circuit's

[1] For this reason, neither Sofamor nor Danek were permitted to participate in the appeal, except as *amicus curiae*. Id. *4 n.3.

decision is not binding on this Court,[2] and any appeal by Hartwell or Still of Judge Bechtle's decision in PTO 845 would be heard by the Fourth Circuit on appeal from this Court.

If plaintiffs move to reinstate their fraud-on-the-FDA claim or move the Court to reconsider Judge Bechtle's ruling in PTO 845, the Court should deny such a motion notwithstanding the Third Circuit's recent decision. First, the Third Circuit's decision does not purport to decide any issues of state law, id. *5 (state law "issues are not before us"), and Virginia does not recognize a claim for fraud-on-the-FDA. Second, the Third Circuit did not address the 1998 FDA Final Rule, id. *4-5, in which the FDA made clear that it had not been defrauded. Third, while a decision of the Third Circuit might usually be of persuasive authority to this Court, the authority of this decision is undermined by the "vehement" dissent, by conflicting authority in the Fourth Circuit and by the significant factual differences present in this case. Finally, it is undisputed that, unlike the AcroMed screws at issue in the Third Circuit case, the TSRH Device was lawfully on the market for sacral use. In both of plaintiffs' surgeries, Dr. Leipzig used the Device for sacral, as well as lumbar, fixation. Since Dr. Leipzig used the Device for its on-label purpose of sacral fixation and since he was unaware of the FDA status of the Device at the time of Hartwell's and Still's surgeries, plaintiffs cannot prove that he used the Device as the result of any alleged fraud-on-the-FDA.

[2] Cf. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 118 S. Ct. 956, 963-64 (1998) (MDL judge without power to assign any part of remanded MDL case to himself).

approved by the FDA." Id. at 1139. The Court declined to interpret the Lanham Act as allowing private assertion of FDCA violations. Id. As in Mylan, Hartwell and Still cannot "by ingenious pleading" escape the FDCA's bar against private enforcement "by making it appear that another not truly appropriate rule is applicable." Id.

Moreover, the Third Circuit decision was based on allegations materially different from those in this case. In the Third Circuit case, plaintiffs alleged that AcroMed represented to the FDA that its screws were intended for use in the "long bones" of the body, even though the screws were marketed and used exclusively in the spine. Orthopedic Bone Screw, 1998 WL 793200 at *5.[4] Here, on the other hand, plaintiffs' allege only that Danek falsely represented to the FDA that the Device was intended for sacral application. Amended Complaint, ¶¶ 102-104, 108. Unlike Buckman and AcroMed, Danek obtained clearance to label and market the TSRH Device for labeling and marketing for a variety of spinal indications, including fixation by bone screws to the pedicles of the sacrum. Further, in both Hartwell's and Still's surgeries, Dr. Leipzig used the Device for sacral fixation. Dr. Leipzig's on-label use of the Device effectively rebuts the claim that Danek's fraudulently obtained clearance of the Device for sacral use merely as a pretext to enable it to market the Device for lumber use. Thus, the facts alleged here are within the distinction recognized by the Third Circuit which stated:

> the situation here alleged bears no resemblance to one in which an applicant for a §510(k) clearance intends to market its device for the use represented, subsequently markets for that use, and, at the same time, responds to direct requests for information from physicians concerning off-label use.

Id. at *18 n.7.

[4] Likewise, in its comments to the FDA regarding the Final Rule, the Plaintiffs' Legal Committee focuses on AcroMed, not Danek. Those comments do not reference any false representations by Danek to the FDA. See *Comments of the Plaintiffs Legal Committee in In re Orthopedic Bone Screw Litigation, MDL Docket 1014, Concerning Proposed Rulemaking* at 34-39; 49-50 (attached as Exh. D).

IV. THE ALLEGED FRAUD DID NOT CAUSE ANY INJURIES TO PLAINTIFFS.

To establish a causative link between the alleged fraud and their surgery, Hartwell and Still claim that if Danek had not fraudulently claimed that the Device was intended for sacral use, the Device would not have been on the market for Dr. Leipzig to use. Amended Complaint, ¶¶ 109, 120. Thus, plaintiffs must prove that but for the alleged fraudulent conduct, the Device would not have been on the market. As a matter of law, plaintiffs cannot meet this burden. First, in the Final Rule, the FDA rejected comments that pedicle screw spinal systems should not be allowed on the market for any use. 63 Fed. Reg. at 40035.

Second, plaintiffs do not allege that the FDA improperly cleared the Device for sacral use. Rather, they claim only that Danek's representations to the FDA regarding the intended use of the Device in the sacrum were false. See Complaint, ¶ 108. Thus, regardless of the alleged fraud, the Device was properly on the market for sacral applications. In both of plaintiff's surgeries, Dr. Leipzig used the Device in the sacrum, conclusively establishing that Danek's request for § 510(k) clearance for sacral use was not merely a pretext to allow Danek to market the Device. Further, Dr. Leipzig did not know the FDA status of the Device at the time of plaintiffs' surgeries. As a result, even assuming that Danek's statements to the FDA about the intended purpose of the Device were fraudulent, the Device would still have been on the market,

and Dr. Leipzig would still have used the Device in plaintiffs' surgeries.[5] As a result, plaintiffs cannot prove that Dr. Leipzig used the Device as the result of any allegedly fraudulent conduct.

CONCLUSION

For the foregoing reasons, defendants respectfully requests that the Court enter summary judgment in their favor on all of the claims asserted by Hartwell and Still and deny any motion to reinstate Count I or to reconsider Judge Bechtle's decision in PTO 845.

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[5] Since learning the regulatory status of the screws, Dr. Leipzig has not changed his practice style and would not have changed his recommended treatment for Hartwell or Still. Deposition of Dr. James Leipzig at 36-37.

No. 98-1768

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

CERTIFICATE OF SERVICE

I, Michael D. Fishbein, counsel for Respondent and a member of the Bar of this Court, hereby certify that on this 4th day of June, 1999, I caused three copies of the Opposition to Motion of Danek Medical, Inc. For Leave to File Brief as *Amicus Curiae* in the above-captioned case to be served on the following counsel of record:

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